

REMARKS

Claim status

Claims 1-6 and 8-17 were currently pending at the time of the advisory action. No claim amendments have been made herein. Claims 1-6 and 8-17 are currently pending in the application.

Office Action of May 11, 2006

In point 4 of the Final Office action of November 2, 2006, the Examiner states that claims 1-18 stand rejected as of the Office action filed May 11, 2006.

Applicants respectfully submit that maintaining the rejections from the Office action of May 11, 2006 is not proper at least because the Office action of May 11, 2006 was responded to by Applicants in the response of August 10, 2006 where claims 1 and 8 were amended and claims 7 and 18 were cancelled.

In a telephone conversation with the Examiner on April 24, 2007, the Examiner stated that this matter had been inherited by him from a previous Examiner and that there did seem to be some confusion in how this matter has been handled by the USPTO as a result of the transition from the previous Examiner to the current Examiner. Therefore, at the request of the current Examiner in our telephone conversation of April 24, 2007, Applicants have addressed both the rejections from the Office action of May 11, 2006 as well as the rejections from the Final Office action of November 2, 2006 such that the Examiner may perform a continued examination of the pending claims to eliminate any confusion and to make a new determination of any allowable claims.

Section 102 rejections (from the Office Action of May 11, 2006)

In the Office action of May 11, 2006, claims 1-3 and 13 were rejected under 35 U.S.C. 102(e) as being anticipated by Esteller et al. (US Patent No. 6,594,524).

Applicants respectfully traverse the foregoing rejections in view of the above pending claims and for reasons set forth hereafter.

Independent claim 1 recites an apparatus for the classification of physiological events, comprising:

- a signal input for the input of a physiological signal representing or constituting a physiological event;

- a classification unit for classifying the physiological signal on the basis of its signal shape, the classification unit comprising:

- a transformation unit which is designed to carry out transformation of the physiological signal in such a way that as the output signal it outputs a number of values representing the physiological signal and based on the transformation; and

- a probabilistic neural network which is connected to the transformation unit to receive the values and which contains a number of event classes which represent physiological events and which in turn are each represented by a set of comparative values, which probabilistic neural network is adapted on the basis of the comparison of the values with the comparative values to effect an association of the physiological signal represented by the values with one of the event classes; and

- an adjusting unit for centering the physiological signal in a time window of predetermined window width and for outputting the centered physiological signal to the transformation unit, the adjusting unit connected upstream of the transformation unit.

It is respectfully submitted that Esteller et al. (U.S. Pat. No. 6,594,524), hereinafter Esteller, does not teach or suggest the invention of independent claim 1. In particular, Esteller does not teach or suggest a centering of a physiological signal in a time window. The physiological signal is centered in the time window in order to avoid the negative effects of an

offset (i.e., an un-centered) signal, which is described in the present application and re-iterated herein below.

Instead, Esteller describes using a running window for the purpose of periodically shifting the window to compute features. Esteller is not concerned at all with generating a centered physiological signal, as is the claimed invention of claim 1, and gives no reason for why one might want to center the physiological signal in a window. Instead, in Esteller, feature extraction is performed through a running window method. A sliding observation window moves through the data as the features are computed. The data points inside the sliding window of Esteller are used for feature generation as the window moves through the data.

The time window of the claimed invention of claim 1 is synchronized with detected events triggering a trigger signal to the adjusting/standardizing stage 28. If the detection stage 26 detects an event, it outputs a trigger signal (triggering signal) to the adjusting/standardizing stage 28 which triggers adjustment and/or standardization of the physiological signal. If the adjusting/standardizing stage 28 receives a trigger signal from the detection stage 26, the underlying IEGM is detected in an event window with a predetermined window width which is generally 64 sampling steps, and centered in the window. The window is adapted to the expected type of event. The procedure also involves ascertaining the time interval from the last-detected event to the present event and standardization of the signal shape to a standardized peak-to-peak amplitude on the basis of a standardization factor in order to obtain a standardized event signal. The adjusting/standardizing stage 28 transmits the time interval and the standardization factor to the probabilistic neural network 5 whereas it transmits the event signal which is standardized and centered in the window to the transformation unit 3.

The information concealed in the input signal is encoded after preparation of the input signal in the signal processing unit 20 in the transformation unit 3 by means of the wavelet transformation procedure. Wavelet transformation however is not invariant in relation to a time shift in the input signal in the signal window, that is to say the result of transformation changes if the maximum of the amplitude is moved forward or back by one or more sampling steps in the signal window. Consequently the values of the coefficients which are outputted by the

transformation unit and which are of substantial significance for classification can fluctuate. The degree of fluctuation depends on the accuracy of centering of the input signal in the signal window.

In the situation involving perfect centering of the signal in the signal window, that is to say in the case of an offset of the value zero, the node which represents the Haversine signal outputs an output value 1 for the Haversine signal as the input signal and an output value of about 0.25 for the triangular signal as the input signal. If on the other hand there is an offset by a sampling step in respect of centering of the Haversine signal or the triangular signal respectively in the signal window (offset + 1 or -1), then the output value for the Haversine signal as the input signal is reduced to about 0.55 and that for the triangular signal as the input signal is reduced to about 0.18.

The difference between the two output values shown in Figure 4 forms the basis of event classification by means of the probabilistic neural network 5. In that respect a great difference (as in the case of the offset 0...i.e., a centered signal) ensures a low level of susceptibility of the classification procedure in relation to signal noise. The reduction in difference by virtue of the offset of +1 or -1 (measured in sampling steps) to approximately half the value with an offset of zero has the result that, in the case of the offset of + 1 or -1 respectively classification errors already occur at noise levels which are half as high as the noise level at which classification errors occur with an offset of zero. That can result in a significant reduction in the operational efficiency of the apparatus, in many uses.

Esteller does not give any suggestion whatsoever to centering a physiological time signal in a time window or to the problems that may arise from an offset, un-centered signal as described above.

Therefore, in view of at least the foregoing, it is respectfully submitted that independent claim 1 is not anticipated by Esteller, and it is respectfully submitted that independent claim 1 defines allowable subject matter. Also, since claims 2-3 and 13 depend either directly or indirectly from claim 1, it is respectfully submitted that claims 2-3 and 13 define allowable

subject matter as well. Applicants respectfully request that the rejection of claims 1-3 and 13 under 35 U.S.C. 102(e) be removed.

Section 103 rejections (from the Office Action of May 11, 2006)

In the Office action of May 11, 2006, claims 4-9, 11-12, and 14-18 were rejected under 35 U.S.C. 103(a) as being unpatentable over Esteller in view of Echauz et al. (US Patent No. 6,678,548).

Applicants respectfully traverse the foregoing rejections in view of the above pending claims and for reasons set forth hereafter.

As described above, Esteller does not teach or suggest a centering of a physiological signal in a time window as does the claimed invention of claim 1. Furthermore, Echauz et al. (US Patent No. 6,678,548), hereinafter Echauz, does not teach or suggest a centering of a physiological signal in a time window as does the claimed invention of claim 1.

Therefore, in view of at least the foregoing and the fact that claims 4-6, 9, 11-12, and 14-17 depend either directly or indirectly from independent claim 1, it is respectfully submitted that claims 4-6, 9, 11-12, and 14-17 define allowable subject matter as well. Claims 7 and 18 have been cancelled. Applicants respectfully request that the rejection of claims 4-9, 11-12, and 14-18 under 35 U.S.C. 103(a) be removed.

In the Office action of May 11, 2006, claim 10 was rejected under 35 U.S.C. 103(a) as being unpatentable over Esteller in view of Echauz and further in view of Igel et al. (US Patent No. 6,192,273).

Applicants respectfully traverse the foregoing rejections in view of the above pending claims and for reasons set forth hereafter.

As described above, Esteller does not teach or suggest a centering of a physiological signal in a time window as does the claimed invention of claim 1. Furthermore, neither Echauz

nor Igel et al. (US Patent No. 6,192,273), hereinafter Igel, teach or suggest a centering of a physiological signal in a time window as does the claimed invention of claim 1.

Therefore, in view of at least the foregoing and the fact that claim 10 depends indirectly from independent claim 1, it is respectfully submitted that claim 10 defines allowable subject matter as well. Applicants respectfully request that the rejection of claim 10 under 35 U.S.C. 103(a) be removed.

Section 103 rejections (from the Final Office Action of November 2, 2006)

In the final Office action of November 2, 2006, claims 1 and 8 were rejected under 35 U.S.C. 103(a) as being unpatentable over Esteller et al. (USPN 6,594,524), hereinafter Esteller, in view of Hively et al. (USPN 6,484,132), hereinafter Hively.

Applicants respectfully traverse the foregoing rejections in view of the above pending claims and for reasons set forth hereafter.

Independent claim 1 recites an apparatus for the classification of physiological events, comprising:

- a signal input for the input of a physiological signal representing or constituting a physiological event;

- a classification unit for classifying the physiological signal on the basis of its signal shape, the classification unit comprising:

- a transformation unit which is designed to carry out transformation of the physiological signal in such a way that as the output signal it outputs a number of values representing the physiological signal and based on the transformation; and

- a probabilistic neural network which is connected to the transformation unit to receive the values and which contains a number of event classes which represent physiological events and which in turn are each represented by a set of comparative values, which probabilistic neural network is adapted on the basis of the comparison of

the values with the comparative values to effect an association of the physiological signal represented by the values with one of the event classes; and

an adjusting unit for centering the physiological signal in a time window of predetermined window width and for outputting the centered physiological signal to the transformation unit, the adjusting unit connected upstream of the transformation unit.

It is respectfully submitted that neither Esteller, Hively, nor the combination thereof teach or suggest the invention of independent claim 1. In particular, neither Esteller, Hively, nor the combination thereof teach or suggest an adjusting unit for centering a physiological signal in a time window of predetermined window width and for outputting the centered physiological signal to the transformation unit, the adjusting unit connected upstream of the transformation unit.

At the bottom of page 11 of the final Office action, the Examiner agrees that Esteller does not teach centering of a physiological signal in a time window.

In the invention of claim 1, the physiological signal is centered in the time window in order to avoid the negative effects of an offset (i.e., an un-centered) signal, which is described in the present application and re-iterated herein below.

Instead, Esteller describes using a running window for the purpose of periodically shifting the window to compute features. Esteller is not concerned at all with generating a centered physiological signal, as is the claimed invention of claim 1, and gives no reason for why one might want to center the physiological signal in a window. Instead, in Esteller, feature extraction is performed through a running window method. A sliding observation window moves through the data as the features are computed. The data points inside the sliding window of Esteller are used for feature generation as the window moves through the data.

The time window of the claimed invention of claim 1 is synchronized with detected events triggering a trigger signal to the adjusting/standardizing stage 28. If the detection stage 26 detects an event, it outputs a trigger signal (triggering signal) to the adjusting/standardizing stage 28 which triggers adjustment and/or standardization of the physiological signal. If the adjusting/standardizing stage 28 receives a trigger signal from the detection stage 26, the

underlying IEGM is detected in an event window with a predetermined window width which is generally 64 sampling steps, and centered in the window. The window is adapted to the expected type of event. The procedure also involves ascertaining the time interval from the last-detected event to the present event and standardization of the signal shape to a standardized peak-to-peak amplitude on the basis of a standardization factor in order to obtain a standardized event signal. The adjusting/standardizing stage 28 transmits the time interval and the standardization factor to the probabilistic neural network 5 whereas it transmits the event signal which is standardized and centered in the window to the transformation unit 3.

The information concealed in the input signal is encoded after preparation of the input signal in the signal processing unit 20 in the transformation unit 3 by means of the wavelet transformation procedure. Wavelet transformation however is not invariant in relation to a time shift in the input signal in the signal window, that is to say the result of transformation changes if the maximum of the amplitude is moved forward or back by one or more sampling steps in the signal window. Consequently the values of the coefficients which are outputted by the transformation unit and which are of substantial significance for classification can fluctuate. The degree of fluctuation depends on the accuracy of centering of the input signal in the signal window.

In the situation involving perfect centering of the signal in the signal window, that is to say in the case of an offset of the value zero, the node which represents the Haversine signal outputs an output value 1 for the Haversine signal as the input signal and an output value of about 0.25 for the triangular signal as the input signal. If on the other hand there is an offset by a sampling step in respect of centering of the Haversine signal or the triangular signal respectively in the signal window (offset + 1 or -1), then the output value for the Haversine signal as the input signal is reduced to about 0.55 and that for the triangular signal as the input signal is reduced to about 0.18.

The difference between the two output values shown in Figure 4 forms the basis of event classification by means of the probabilistic neural network 5. In that respect a great difference (as in the case of the offset 0...i.e., a centered signal) ensures a low level of susceptibility of the

classification procedure in relation to signal noise. The reduction in difference by virtue of the offset of +1 or -1 (measured in sampling steps) to approximately half the value with an offset of zero has the result that, in the case of the offset of + 1 or -1 respectively classification errors already occur at noise levels which are half as high as the noise level at which classification errors occur with an offset of zero. That can result in a significant reduction in the operational efficiency of the apparatus, in many uses.

Esteller does not give any suggestion whatsoever to centering a physiological time signal in a time window or to the problems that may arise from an offset, un-centered signal as described above.

In the final Office action, the Examiner states that Hively teaches an adjusting unit where “the apparatus including a data collector” is the adjusting unit (see col. 2, lines 43-46), for centering the physiological signal in a time window of predetermined window width and for outputting the centered physiological signal to the transformation unit (see col. 14, lines 50-54), the adjusting unit connected upstream of the transformation unit (see col. 2, lines 43-46). The Examiner interprets the “apparatus including a data collector” to be an adjusting unit used as a data collector upstream from the transformation unit (see col. 3, lines 1-8).

However, Applicants respectfully do not agree that Hively teaches or suggests any adjusting unit for centering a physiological signal within a time window. A data collector can be anything like, for example, a simple sample and hold circuit that does not comprise any means for centering a physiological signal in a time window.

In the claimed invention, the signal that is to be wavelet analyzed is an IEGM signal that is an almost periodic signal. That is, the signal comprises parts that are nearly similar to each other but that do not precisely re-occur in highly regular periods of time. Therefore, the IEGM signal to be wavelet transformed is centered within an event window that is started by a trigger signal from the event detection stage of the claimed invention (see paragraph [0030] of the present application).

Again, Hively does not teach or suggest such an adjusting unit for centering a physiological signal in a time window of predetermined window width and for outputting the

centered physiological signal to the transformation unit, the adjusting unit connected upstream of the transformation unit. In col. 14, lines 50-54, when Hively describes plotting the non-linear measures at the center of the time window for each cutset, Hively is not referring to centering of the signal in the time dimension as in the claimed invention but, instead, centering of the signal vertically in the amplitude dimension for the purpose of plotting (see Fig. 2a). The time window referred to by Hively is over many seconds (e.g., 0 to 2200 seconds in Fig. 2). Such a time window of Hively is not similar to the time window of the claimed invention where the time window of the claimed invention is an event window with a predetermined window width (e.g., 64 samples at a sampling rate of 1024 samples per second). Such a window width of the claimed invention might be, for example, only 64 milliseconds, not hundreds of seconds as in Hively. Furthermore, Hively is not doing any centering of a signal in a time dimension. Hively is concerned with looking for global trends over many hundreds of seconds. The claimed invention is concerned with processing signals representing physiological events centered in windows of very short duration (e.g., milliseconds). Therefore, the data collector of Hively cannot be considered an adjusting unit in the sense of the claimed invention of claim 1 since Hively does not describe doing any such adjusting (i.e., centering of a physiological signal in a time window). The purpose of centering the physiological signal in a time window of a predetermined width in the claimed invention of claim 1 is to reduce susceptibility to signal noise. Hively does not discuss or suggest trying to reduce susceptibility to signal noise by signal centering in the time dimension.

Therefore, in view of at least the foregoing, it is respectfully submitted that independent claim 1 is not unpatentable over Esteller in view of Hively, and it is respectfully submitted that independent claim 1 defines allowable subject matter. Also, since claim 8 depends either directly or indirectly from claim 1, it is respectfully submitted that claims 8 defines allowable subject matter as well. Applicants respectfully request that the rejection of claims 1 and 8 under 35 U.S.C. 103(a) be removed.

In the final Office action, claims 4, 11, and 12 were rejected under 35 U.S.C. 103(a) as being unpatentable over Esteller in view of Echauz et al. (US Patent No. 6,678,548), hereinafter, Echauz.

Applicants respectfully traverse the foregoing rejections in view of the above pending claims and for reasons set forth hereafter.

As described above and as admitted by the Examiner, Esteller does not teach or suggest a centering of a physiological signal in a time window as does the claimed invention of claim 1. Furthermore, Echauz et al. (US Patent No. 6,678,548), hereinafter Echauz, does not teach or suggest a centering of a physiological signal in a time window as does the claimed invention of claim 1.

Therefore, in view of at least the foregoing and the fact that claims 4, 11, and 12 depend either directly or indirectly from independent claim 1, it is respectfully submitted that claims 4, 11, and 12 define allowable subject matter as well. Applicants respectfully request that the rejection of claims 4, 11, and 12 under 35 U.S.C. 103(a) be removed.

In the final Office action, claim 10 was rejected under 35 U.S.C. 103(a) as being unpatentable over Esteller in view of Echauz and further in view of Igel et al. (US Patent No. 6,192,273).

Applicants respectfully traverse the foregoing rejections in view of the above pending claims and for reasons set forth hereafter.

As described above and as admitted by the Examiner, Esteller does not teach or suggest a centering of a physiological signal in a time window as does the claimed invention of claim 1. Furthermore, neither Echauz nor Igel et al. (US Patent No. 6,192,273), hereinafter Igel, teach or suggest a centering of a physiological signal in a time window as does the claimed invention of claim 1.

Therefore, in view of at least the foregoing and the fact that claim 10 depends indirectly from independent claim 1, it is respectfully submitted that claim 10 defines allowable subject

matter as well. Applicants respectfully request that the rejection of claim 10 under 35 U.S.C. 103(a) be removed.

In the final Office action, claims 2, 3, 5, 6, 9, and 14-17 were rejected under 35 U.S.C. 103(a) as being unpatentable over Esteller.

Applicants respectfully traverse the foregoing rejections in view of the above pending claims and for reasons set forth hereafter.

As described above and as admitted by the Examiner, Esteller does not teach or suggest a centering of a physiological signal in a time window as does the claimed invention of claim 1.

Therefore, in view of at least the foregoing and the fact that claims 2, 3, 5, 6, 9, and 14-17 depend either directly or indirectly from independent claim 1, it is respectfully submitted that claims 2, 3, 5, 6, 9, and 14-17 define allowable subject matter as well. Applicants respectfully request that the rejection of claims 2, 3, 5, 6, 9, and 14-17 under 35 U.S.C. 103(a) be removed.

Accordingly, the applicant respectfully requests reconsideration of the rejections and objections based on at least the foregoing. After such reconsideration, it is urged that allowance of claims 1-6 and 8-17 will be in order.

Respectfully submitted,



David J. Muzilla
Registration No. 50,914

Hahn Loeser & Parks LLP
One GOJO Plaza
Suite 300
Akron, OH 44311-1076
(330) 864-5550
Fax 330-864-7986
djmuzilla@hahnlaw.com

CUSTOMER No. 021324